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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, v. ZYDUS PHARMACEUTICALS USA INC. and CADILA HEALTHCARE LIMITED, Defendants.	CIVIL ACTION NO: 3:10-CV-01723-JAP-TJB **[ORAL ARGUMENT REQUESTED]**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR RECONSIDERATION OF CLAIM CONSTRUCTION

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Pursuant to Local Civil Rule 7.1(i), Defendants Zydus Pharmaceuticals, USA, Inc. and Cadila Healthcare, Limited (collectively "Zydus") respectfully request that the Court reconsider and vacate a portion of its October 5, 2011 Order and Opinion (Docket Nos. 113 - 114), wherein the Court issued its detailed claim construction ruling on disputed patent terms. This motion addresses the Court's construction of two phrases found in U.S. Patent No. 6,328,994 (the "'994 patent") and U.S. Patent No. 7,431,942 (the "'942 patent")[1]: "average particle diameter of 400 μm or less" and "average particle diameter of … 300 to 400 μm." In addition to this memorandum of law, Zydus relies on the Declaration of Vincent P. Rao II ("Rao Decl.") dated October 19, 2011.

PRELIMINARY STATEMENT

The Court's construction of the phrase "fine granules having an average particle diameter of 400 μm or less" to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 μm (±10%) or less" in respect of the '994 patent, and fine granules having "average particle diameter of … 300 to 400 μm" to mean an "average particle diameter of 300 to 400 μm (±10%)" in respect of the '994 and '942 patents, necessarily overlooks controlling Federal Circuit case law to the effect that a claim construction should not be inconsistent with the specification. Here, the Court overlooked that its construction, allowing for values of the "fine granules" to be significantly above

[1] *See* Docket No. 69-2, Exhibits 1 and 2 to the Moriarty Decl., respectively.

400 μm, is completely at odds with the '994 and '942 patent specifications, which expressly criticize and disavow prior art containing large particle diameter granules defined as having 400 μm or more of average particle diameter.

The Court's construction of this phrase also overlooks Zydus' arguments that, 1) it is inappropriate under controlling case law to read "fine granules" to include "large granules" as such terms were mutually exclusively defined in the specification, and 2) the maximum particle diameter size as set forth in the specification - by mere application of mathematical principles - prohibits an average particle diameter of 440 μm - regardless of whether such "average" references the median or the mean.

Lastly, the Court's decision, based solely on disfavored extrinsic expert testimony, is predicated on a fundamental misreading of a portion of a U.S. Pharmacopeia document as relating to the accuracy of laser diffraction machines, which document, on its face, indisputably supports Zydus' position that laser diffraction machines must have an inaccuracy of no more than ±3%.

For all the foregoing reasons, Zydus respectfully requests that the Court reconsider its claim construction ruling in regard to such terms, and to modify the same by allowing a variance in diameter of ±3% rather than ±10%.[2]

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[2] In addition, irrespective of the Court's finding that the patentee did not "clear[ly] and unmistakabl[y]" disavow direct compression sugars, sucrose or lactose, in the prosecution history of the term "disintegrating agent" in U.S. Patent No. 5,464,632, (Docket No. 69-2, Ex. 3 to the Moriarty Decl.), Zydus seeks clarification that, under controlling Federal Circuit case law,

ARGUMENT

I. LEGAL STANDARD FOR RECONSIDERATION

Motions for reconsideration are appropriate when the Court has overlooked issues critical to a full apprehension of the matter at issue. Local Civil Rule 7.1(i). "The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l*, 602 F.3d 237, 251 (3d Cir. 2010). A judgment may be altered if it is necessary to correct a clear error of law or prevent manifest injustice, among other reasons. *Yurecko v. Port Auth. Trans-Hudson Corp.*, 279 F. Supp. 2d 606, 609 (D.N.J. 2003). Respectfully, this motion for reconsideration is necessary to correct a clear error of law and fact to prevent manifest injustice.

The Court necessarily overlooked dispositive case law (in construing the literal scope of a claim to cover prior art alternatives criticized and disavowed in the specification), and material facts (in misconstruing a statement in a technical

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Plaintiffs remain collaterally estopped from propounding a construction of claim terms to cover such sugars, particularly to the extent Judge Robinson's claim construction of the same in *Takeda Pharm. Co. Ltd. v. Teva Pharms. USA, Inc.*, 668 F. Supp. 2d 614 (D. Del. 2009) was essential to the judgment on the issue of infringement in that case. As set forth in Zydus's responsive claim construction brief, (pp. 26-27), if non-infringement was found in a prior case, then the prior claim interpretation has issue preclusive effect. *Pfaff v. Wells Elec., Inc.*, 5 F.3d 514, 518 (Fed. Cir. 1993); *Molinaro v. Fannon/Courier Corp.*, 745 F.2d 651, 655 (Fed. Cir. 1984) ("a second defendant is entitled to the benefit of a judgment issued against the plaintiff in favor of a first defendant in prior litigation on the same issues."). Judge Robinson's finding of file wrapper estoppel, in respect to compression sugars not being within the ambit of the phrase "disintegrant," has estoppel effect against plaintiffs, irrespective of the Court's opinion that Judge Robinson's file wrapper estoppel citation did not constitute an express disclaimer.

article to relate to the accuracy of a laser diffraction machine when the accuracy of such machines is specified two pages later in the same reference), originally presented in the claim construction briefing and hearing in rendering its decision. *See Ciba-Geigy Corp. v. Alza Corp.*, 1993 WL 90412, at *1-2 (D.N.J. March 25, 1993) ("The Court may grant a motion for reconsideration where it overlooked a factual or legal issue that may alter the disposition of the matter."); *Leja v. Schmidt Mfg., Inc., 2011 WL 3684845*, at *4 (D.N.J. Aug. 22, 2011).

II. THE CONSTRUCTION OF "FINE GRANULES HAVING AN AVERAGE PARTICLE DIAMETER OF 400 MM OR LESS" IN THE '994 PATENT, AND "AVERAGE PARTICLE DIAMETER OF 300 TO 400 MM" IN THE '994 AND '942 PATENTS, TO INCLUDE GRANULES WITH AVERAGE PARTICLE DIAMETERS OF AS MUCH AS 440 μM IS CONTRARY TO THE INTRINSIC EVIDENCE

A. The Intrinsic Evidence Clearly Demonstrates "Fine Granules" Of The Claims Cannot Be Read To Include Disavowed Conventional Granules Having "Large Particle Diameters"

In their opening claim construction brief and the hearing before this Court[3], Defendants noted that an interpretation of "fine granules having an average particle diameter of 400 μm or less" to include particles above "400 μm" would, contrary to controlling case law, allow the claims to read on disavowed, criticized, and distinguished particles of the prior art as set forth in the specification of the '994 and '942 patents. In formulating its construction of "fine granules having an

[3] Docket No. 69, p.12; Markman Presentation, slides 10-12; Transcript of May 26, 2011 Markman Hearing, p.33, ln.18-p.36, ln.12 (Excerpts of the Markman Presentation and the Markman Transcript are attached to the Rao Decl. as Exhibits 1 and 2, respectively).

average particle diameter of 400 μm or less," the Court erred by overlooking the primacy of the intrinsic evidence with respect to claim construction, as opposed to the extrinsic evidence relied upon by the Court in reaching its ±10% construction.

As set forth in Zydus' opening and responsive claim construction briefs,[4] *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) requires that intrinsic evidence be given primacy over any extrinsic evidence when construing a claim term. The *Phillips* court noted that the specification must be given "dispositive" effect over all other evidence when, as here, the "specification … reveal[s] an intentional disclaimer, or disavowal of claim scope by the inventor." *Id. at 1316* (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

Disclaimer or disavowal is found in particular "where the general summary or description of the invention describes a feature of the invention … and criticizes other products … that lack the same feature." *Edward Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1333 (Fed. Cir. 2009) (citation omitted). In *AstraZeneca AB v. Mutual Pharm., Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004), the court held that "expressions of manifest exclusion or restriction" are not required for disavowal of

[4] Docket No. 69, p.7 ("However, such *extrinsic* evidence is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence."); Docket No. 80, p.6 ("As recognized in *Phillips v. AWH Corp.*, however, extrinsic evidence is inherently less reliable than intrinsic evidence, and cannot be used 'to change the meaning of claims in derogation of the indisputable public records consisting of the claims, the specification and the prosecution history, thereby undermining the public notice function of patents.'" 415 F.3d at 1319.).

the claim scope of a term. Preclusive disclaimer is also found when the prior art is distinguished from the asserted invention. *See Retractable Tech., Inc. v. Becton, Dickinson and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (finding disclaimer because "specifications expressly recite that the 'invention' has a body constructed as a single piece and expressly distinguish the invention from the prior art based on this feature."). In short, it is simply "not reasonable to read the claims as reading on a prior art configuration which was expressly addressed and remedied by the [] patent." *Ex Parte Jorgen J. Moller, Jr.*, Appeal No. 2010-012534, Reexamination Control 90/009,124 (BPAI January 27, 2011).

The '994 and '942 patents both emphatically state, under the heading "Industrial Applicability," that a feature of all of the orally disintegrable tablets is that "the orally disintegrable tablet of the present invention contains fine granules having the average particle diameter and an enteric coating layer such that it will not impart roughness in the mouth, it can be administered easily without discomfort ..."[5] (emphasis added). The "Background Art" section disparages prior art conventional granules "having a large particle diameter (400 μm or more of average particle diameter)" because they "produce a feeling of roughness in the

[5] '994 patent Col. 37, ln. 21 - 26; '942 patent Col. 37, ln. 32- 36.

mouth."[6] This clear disavowal of particles with an average particle diameter of 400 μm or more precludes reading "400 μm or less" to mean as much as 440 μm.

B. The Intrinsic Evidence Clearly Defines "Fine Granules" As Mutually Exclusive Of Granules Of "Large Particle Diameter"

The definitions provided in the "Background Art" section with regard to granules of "large particle diameter" (*i.e.*, "400 μm or more of average particle diameter") and the "Disclosure of Invention" section with regard to "fine granules" ("'fine granules' have an average particle diameter of about 400 μm or less, preferably 350 μm or less"[7]) further clarify that the inventors, as their own lexicographers, specifically distinguished prior art "large particle diameters," from the "fine granules" of the invention. As such, "fine granules having an average particle diameter of 400 μm or less" or fine granules having an "average particle diameter of … 300 to 400 μm" cannot be read to encompass granules having an average particle diameter of 440 μm because it would be wholly contrary to the drafters' own distinction between "large" and "fine" granules.

As illustrated below, construing the element "fine granules having an average particle diameter of 400 μm or less" to include granules with average particle diameters of 440 μm or less causes the claim to include granules specifically excluded by both the express definitions in the specification (allowing large granules to be fine granules), and by disavowal:

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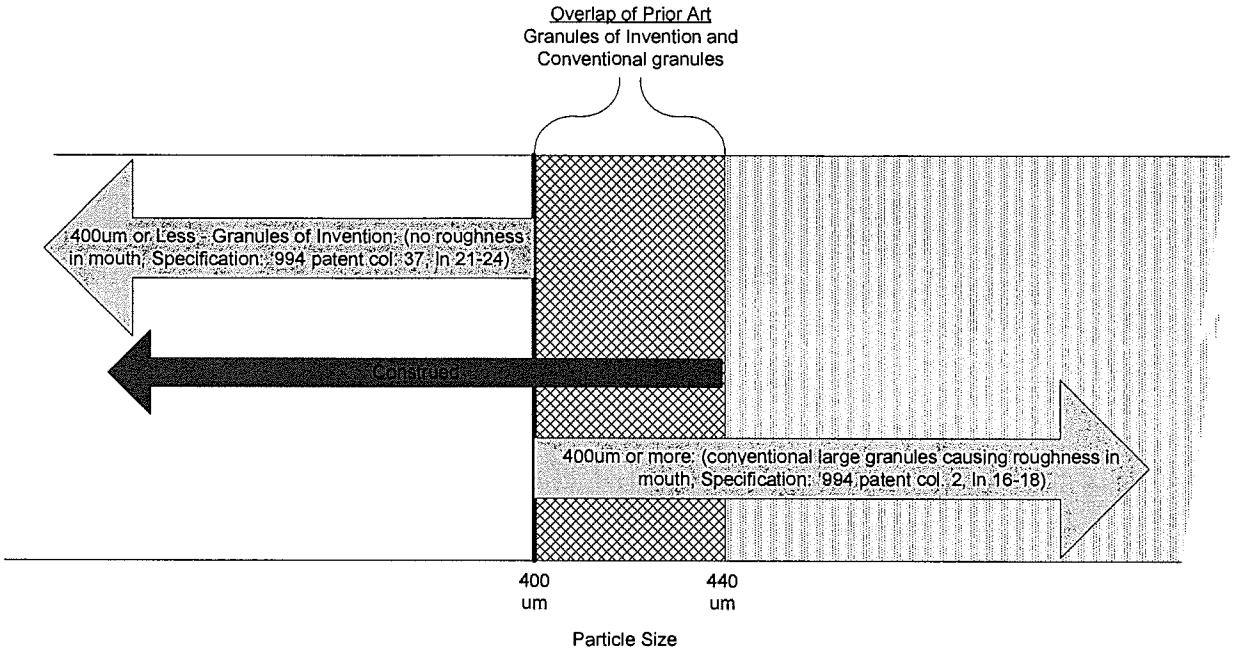
6 '994 patent, Col. 2, ln. 16 - 17; '942 patent, Col. 2 , ln. 19 - 20.

7 '994 patent, Col. 12, ln. 58 - 61; '942 patent, Col. 2, ln. 41 - 44.



When the specification makes clear that terms are different and mutually exclusive of one another, one cannot read those terms as having overlapping constructions. *See Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1210 (Fed. Cir. 2002). Where the "specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims … even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Sys.*, 242 F.3d at 1341; *see also Plastpro, Inc. v. Therma-Tru Corp.*, 378 F. Supp. 2d 519, 525 (D.N.J. 2005).

C. The Intrinsic Evidence Clearly Demonstrates That The "Fine Granules" Of The Claims Cannot Be Read To Include Granules With A Median Or Mean Diameter Of 440 µm

The court further overlooks Zydus' Markman hearing argument that the "average particle diameter" of the fine granules cannot be as high as 440 µm

because that would place the average particle diameter substantially above the maximum allowable particle diameter permitted by the specification[8]:

> Aside from the average particle diameter of the above 'fine granules,' **regarding the maximum particle size, the particle diameter is practically 425 μm or less**, and preferably practically 400 μm or less.

See '994 patent, col. 5, ln. 65 - col. 6, ln. 1 (emphasis added). The specification asserts that "practically" as used in "the particle diameter is practically 425 μm or less" means:

> The particles may include a small quantity (**about 5 weight % or less**) of particles whose particle diameter is out of [the] [sic] above described range **to include the inevitable contaminant particles**.

See '994 patent, col. 6, ln. 3 - 10 (emphasis added). Thus, the fine particles of maximum size may include "contaminant particles" whose particle diameter is greater than 425 μm, as long as such contaminant particles do not exceed more than about 5 percent of the weight of the particles being measured.

The Court has found no construction being necessary for the phrase "average particle diameter"[9] leaving it to expert testimony as to what was meant by the

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[8] Rao Decl., Ex. 1, Slide 26; Rao Decl., Ex. 2, Transcript p.38, ln.2-p.44, ln.1.

[9] This decision was made irrespective of Zydus showing at the Markman hearing that in a declaration under 37 CFR 1.132 (Paper No. 9 in the file history of the '994 Patent), the inventors distinguished prior art (EP 761 212 A2) in respect of the non-obviousness of the formulations by providing the Patent Office "average particle diameters" that were equated to the volume based distribution median by the declarant. (Rao Decl., Ex. 1, Slide 12B; Rao Decl., Ex. 2, Transcript p.44, ln.4 – p.44, ln.13). Zydus repeats their concern that controlling case law mandates that Plaintiffs are estopped from asserting that the phrase "average particle diameter" is equivalent to "mean

terminology in the claims. Irrespective of whether the term "average particle diameter" references the mean or median particle diameter, it is mathematically impossible for the fine particles to have either a median or mean particle diameter that is 440 μm (even assuming that all of the particles other than the contaminant particles are at their maximum particle diameter), as discussed further below.

1. Given The Maximum Particle Size Diameter Set Forth In The Specification, The Median Diameter Of The Fine Granules Of The Claims Mathematically Can NEVER Be As High As 440 μm

The median of a list of items represents the middle; it is found by ranking all items from lowest value to highest value and picking the middle one. Because its value is based on its middle position in the distribution, the median value is not sensitive to a tiny fraction of very small or very large items at either end of the size distribution. In the present case, given that the contaminant particles will have the same density as the fine particles in which they may be found, the contaminant particles can never move the maximum median particle diameter above 425 μm because the number of contaminant particles is simply too small to affect the median value. For example, as illustrated in the diagram below, **A** shows a median value of 95 particles, with a maximum 425 μm diameter size, and 1 large contaminant particle (727 μm) comprising 5 weight percent of the total. The

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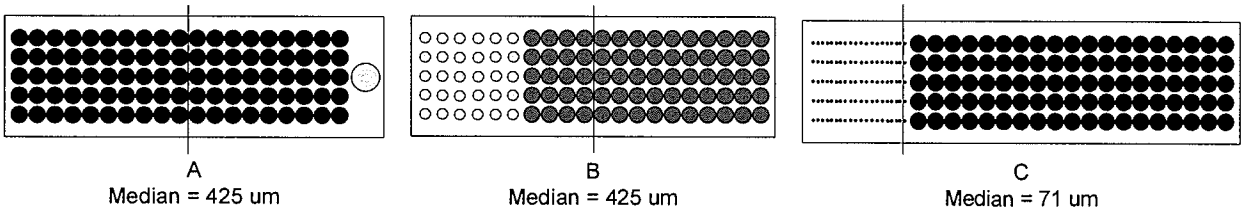
particle diameter." *See, e.g., Day Int'l, Inc. v. Reeves Bros., Inc.*, 260 F.3d 1343, 1350 (Fed. Cir. 2001) (arguments distinguishing invention from prior art limited ordinary meaning of claim).

median value is 425 μm. Likewise, **B** shows a more exaggerated case wherein the median value of 70 particles of 425 μm maximum diameter size, combined with 30 smaller particles of half the size (comprising 5 wt% of the total). The median is still 425 μm. In fact, the median particle diameter can only shift downward if the sample is filled with a large number of particles smaller than 425 μm, as illustrated in **C**, with 100 very small particles (71 μm diameter) and 95 large particles (425 μm diameter), as compared to **A** and **B**.



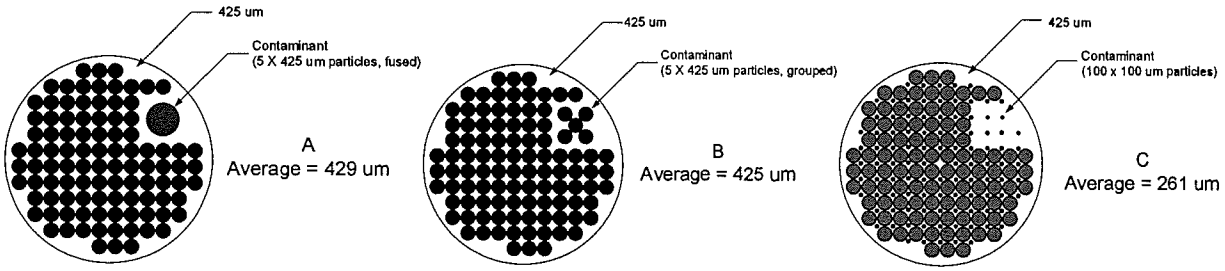
2. Given The Maximum Particle Size Diameter Set Forth In The Specification The Mean Diameter Of The Fine Granules Of The Claims Mathematically Can NEVER Be As High As 440 μm

The arithmetic mean is found by adding up all the numbers of a measurement and dividing by the amount of numbers. The maximum contaminant ratio allowed by the phrase "practically" in "practically 425 μm or less" (the specified "maximum particle size" diameter[10] is "about 5 weight % or less."[11] Again, because the contaminants result from the same composition comprising the "fine granules," the density of the compositions must be the same or substantially

[10] '994 Patent, Col. 5, ln. 65 - Col. 6, ln. 3; '942 Patent, Col. 5, ln. 52 – 56.

[11] '994 Patent, Col. 6, ln. 4 - 9; '942 Patent, Col. 5, ln. 57 – 62.

the same. With the limitation of "about 5 weight % or less" for contaminants, there is no mathematical possibility that the mean particle diameter of the mixture can reach 440 µm (even if all particles, except for the contaminants particles, are at the specified maximum particle diameter of 425 µm - that is if 95% of the particles are at 425 µm in diameter, while the remaining 5% by weight of contaminants are at another diameter). In fact, given the largest possible mean particle diameter for the contaminants (assuming one large contaminant) in the mixture at 5 wt%, the mean would be, at the most, on the high end 429 µm, as illustrated below[12]:



III. THE CONSTRUCTION OF "FINE GRANULES HAVING AN AVERAGE PARTICLE DIAMETER OF 400 MM OR LESS" IN THE '994 PATENT AND "AVERAGE PARTICLE DIAMETER OF 300 TO 400 MM" IN THE '994 AND '942 PATENTS, TO INCLUDE GRANULES WITH AVERAGE PARTICLE DIAMETERS OF AS MUCH AS 440 MM OVERLOOKS PLAINTIFFS' OWN EXTRINSIC EVIDENCE

A. The Court Clearly Misconstrues The US Pharmacopeia Document Supplied By Plaintiffs

The Court finds the accuracy of laser diffraction machines to be dispositive regarding the variability allowed with respect to the average particle diameters

[12] Large enough numbers of contaminant particles with diameters above 425 um to cause an increase in mean particle size to anything near 440 µm are not possible due to the limitation on the weight percent of contaminants.

referenced in the claims. The Court has construed Plaintiffs' expert's testimony (Dr. Byrn) to assert that "a deviation of 10% for measurement by laser diffraction particle distribution is universally accepted" and maintains that the "state of the technology is such that its accuracy" is reflected by a 10% variability. However, nothing is farther from the truth as clearly set forth in the US Pharmacopeia reference provided by Dr. Byrn himself.

As noted by Zydus during the Markman hearing,[13] the provision cited by Dr. Byrn relates to the maximum variability allowed by U.S. Pharmacopeia <429> in respect of multiple granule measurements of bulk manufactured products (which, unlike the Court's construction, requires an analytical variance in every case of less than ±10%, *i.e.* not including 10% variance). In other words, it relates to the maximum possible variation in respect to the uniformity of a bulk production.

The U.S. Pharmacopeia specifically notes that even with respect to measurements in batch manufacturing, however, "[t]he required precision of the method is dependent on the characteristics of the material … and also on the requirements of application (formulation type[14] and technique)." (emphasis

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13 Rao Decl., Ex. 2, Transcript at p.36, ln.17 – p.42, ln. 3.

14 "Formulation Type" can relate, for example, to "orally disintegratable tablets" which require a particularly tight granule size to cause fast disintegration, versus a standard tablet where disintegration time is not critical.

added).[15] Thus, the section cited by Dr. Byrn has nothing to do with the accuracy of the laser diffraction instruments which the Court finds critical to construction.

The accuracy of the state of technology, however, is clearly set forth at page 1051 (*Id.*, under the heading "accuracy and repeatability"). Here it is specified that the laser diffraction instrument must, with respect to a standard reference material[16] be able to repeatedly measure the mean particle diameter (= x_{50}) with no more than 3% variability.[17] To measure to 3%, of course, the machine must have an intrinsic accuracy better than 3%. This is in line with Defendant's assertion in its opening claim construction brief that the intrinsic evidence of the patent, as shown in the examples, clearly demonstrates high accuracy of the instrument in that the measurements are reported down to a tenth of a micrometer (in one case distinguishing between 326.6 μm and 326.9 μm - a difference of only .3 μm).[18]

This without doubt supports Zydus' assertion that a commercial instrument at the time of the application (the relevant time frame) could "easily achieve a relative standard deviation less than 3%"(indeed, the U.S. Pharmacopeia mandates such accuracy even today).

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15 Docket No. 70-1, Byrn Declaration Ex. 5, US Pharmacoepia, Section <429> Light Diffraction Measurement of Particle Size, pp. 1044 - 1052, at p. 1050.

16 Which material is comprised of a particle distribution with a defined average particle diameter.

17 *Id.* at p. 1051: "The response of a laser diffraction instrument is considered adequate if the mean value of x_{50} obtained from at least three independent measurements does not exceed the certified range of values of the certified or standard reference material by more than 3%."

18 '994 Patent, Col. 24, ln. 15-16, Col. 26, ln. 8-9.

CONCLUSION

For the foregoing reasons, Zydus respectfully requests that the Court alter its October 5, 2011 Opinion and Order and vacate its Claim Construction of the disputed terms in Claims 1 and 2 of the '994 patent, and claim 1 of the '942 patent, and modify the same by allowing a variance in diameter of no more than ±3%. In the alternative, as the Court relies on suspect extrinsic evidence for its construction with respect to these terms, it should respectfully decline to specifically construe these claim terms with respect to variance, finding such terms to have ordinary and customary meaning as to one skilled in the art, thereby allowing for competing expert testimony on the subject.

Dated: October 19, 2011

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